IVERMECTIN- ivermectin paste JEFFERS

JEFFERS Ivermectin (ivermectin) Paste 1.87%

Anthelmintic and Boticide □

Removes worms and bots with a single dose.

Contents will treat up to 1250 lb body weight.

FOR ORAL USE IN HORSES ONLY.

KEEP OUT OF REACH OF CHILDREN.

ANADA 200-326, Approved by FDA

Net Wt. 0.21 oz (6.08 g)

INDICATIONS: Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism. IVERMECTIN (ivermectin paste) provides effective treatment and control of the following parasites in horses. Large Strongyles (adults)- Strongylus vulgaris (also early forms in blood vessels), S. edentatus (also tissue stages), S. equinus, Triodontophorus spp. including T. brevicauda and T. serratus and Craterostomum acuticaudatum; Small Strongyles (adults, including those resistant to some benzimidazole class compounds)-Coronocyclus spp. including C. coronatus, C. labiatus and C. labratus, Cyathostomum spp. including C. catinatum and C. pateratum, Cylicocyclus spp. including C. insigne, C. leptostomum, C. nassatus, and C. brevicapsulatus, Cylicodontophorus spp., Cylicostephanus spp. including C. calicatus, C. goldi, C. longibursatus and C. minutus, and Petrovinema poculatum; Small Strongyles -Fourth-stage larvae; **Pinworms** (adults and fourth-stage larvae)-Oxyuris equi; **Ascarids** (adults and third- and fourth-stage larvae)- Parascaris equorum; Hairworms (adults)-Trichostrogylus axei; Large-mouth Stomach Worms (adults)- Habronema muscae; **Bots** (oral and gastric stages)-Gasterophilus spp. including G. intestinalis and G. nasalis; Lungworms (adults and fourth-stage larvae)- Dictyocaulus arnfieldi; Intestinal Threadworms(adults)- Strongyloides westeri; Summer Sorescaused by Habronema and *Draschia* spp. cutaneous third-stage larvae; Dermatitis caused by neck threadworm microfilariae, Onchocerca sp.

DOSAGE: This syringe contains sufficient paste to treat one 1250 lb horse at the recommended dose rate of 91 mcg ivermectin per lb (200 mcg/kg) body weight. Each weight marking on the syringe plunger delivers enough paste to treat 250 lb body weight.

Do not underdose. Ensure each animal receives a complete dose based on a current body weight. Underdosing may result in ineffective treatment, and encourage the development of parasite resistance.

PARASITE CONTROL PROGRAM: All horses should be included in a regular parasite control program with particular attention being paid to mares, foals and yearlings. Foals should be treated initially at 6 to 8 weeks of age, and routine treatment repeated as appropriate. Consult your veterinarian for a control program to meet your specific needs. IVERMECTIN (ivermectin paste) effectively controls gastrointestinal nematodes and bots of horses. Regular treatment will reduce the chances of verminous arteritis

caused by Strongylus vulgaris.

PRODUCT ADVANTAGES: Broad-spectrum Control - IVERMECTIN kills important internal parasites, including bots and the arterial stages of *S. vulgaris*, with a single dose. IVERMECTIN is a potent antiparasitic agent that is neither a benzimidazole nor an organophosphate.

ANIMAL SAFETY: IVERMECTIN (ivermectin paste) may be used in horses of all ages, including mares at any stage of pregnancy. Stallions may be treated without adversely affecting their fertility.

STORAGE INFORMATION: Store at68°F - 77°F (20°C - 25°C). Excursions between 59°F - 86°F (15°C - 30°C) are permitted.

ADMINISTRATION:

- (1) While holding plunger, turn the knurled ring on the plunger 1/4 turn to the left and slide it so the side nearest the barrel is at the prescribed weight marking, aligning the arrow on the ring to the line between the weight and lbs, as shown in the pictogram.

 (2) Lock the ring in place by making a 1/4 turn to the right. Ensure

- (3) Make sure that the horse's mouth contains no feed.
- (4) Remove the cover from the tip of the syringe.

it is locked (it should no longer slide).

- (5) Insert the syringe tip into the horse's mouth at the space between the teeth.
- (6) Depress the plunger as far as it will go, depositing paste on the back of the tongue.
- (7) Immediately raise the horse's head for a few seconds after dosing.

WARNING: Do not use in horses intended for human consumption.

Not for use in humans. Keep this and all drugs out of reach of children. Refrain from smoking and eating when handling. Wash hands after use. Avoid contact with eyes. The Safety Data Sheet (SDS) contains more detailed occupational safety information. To report suspected adverse drug events, for technical assistance, or to obtain a copy of the SDS contact Bimeda, Inc. at 1-888-524-6332. For additional information about adverse drug experience reporting for animal drugs, contact FDA at 1-888-FDA-VETS or www.fda.gov/reportanimalae.

PRECAUTIONS: IVERMECTIN (ivermectin paste) has been formulated specifically for use in horses **only**. This product should not be used in other animal species as severe adverse reactions, including fatalities in dogs, may result.

OTHER WARNINGS: Parasite resistance may develop to any dewormer, and has been reported for most classes of dewormers.

Treatment with a dewormer used in conjunction with parasite management practices appropriate to the geographic area and the animal(s) to be treated may slow the development of parasite resistance.

Fecal examinations or other diagnostic tests and parasite management history should be used to determine if the product is appropriate for the herd prior to the use of any dewormer. Following the use of any dewormer, effectiveness of treatment should be monitored (for example, with the use of a fecal egg count reduction test or another appropriate method).

A decrease in a drug's effectiveness over time as calculated by fecal egg count reduction tests may indicate the development of resistance to the dewormer administered. Your parasite management plan should be adjusted accordingly based on regular monitoring.

Environmental Safety: Ivermectin and excreted ivermectin residues may adversely affect aquatic organisms. Do not contaminate ground or surface water. Dispose of the syringe in an approved landfill or by incineration.

INFORMATION FOR HORSE OWNERS: Swelling and itching reactions after treatment with IVERMECTIN (ivermectin paste) have occurred in horses carrying heavy infections of neck threadworm (Onchocerca sp.) microfilariae. These reactions were most likely the result of microfilariae dying in large numbers. Symptomatic treatment may be advisable. Consult your veterinarian should any such reactions occur. Healing of summer sores involving extensive tissue changes may require other appropriate therapy in conjunction with treatment with IVERMECTIN. Reinfection, and measures for its prevention, should also be considered. Consult your veterinarian if the condition does not improve.

WARNING: Do not use in horses intended for human consumption. Not for use in humans. Keep this and all drugs out of read-of children. Referin first miching and existing when hands have use. Associated coreact with eyes. The Safety (last Sheet (DS)) contains more detailed compatibilist safety internation. To expect advanced request, for sectional adultance or to chain a copy of the SSS, context Brinds, inc. at 1-866-524-6332. For additional information about above drop seperiors reporting in arrand longs, central FDA information about all reporting the same language of PREGAUTIONS: VERMECTIN (poemicicia) passed has been farmulated specifically PREGAUTIONS: VERMECTIN (poemicicia) passed has been farmulated specifically

for use in horses only. This product should not be used in other arimal species as severe advence excrisos, including featilities in days, may result.

OTHER WARNINGS: Peasure resistance may develop to any dewormer, and has been period for note closes of dewormers.

Beatment with a dewormer used in conjunction with parasite management practices paperpostate to the geographic area and the animals) to be trooted may show the development of practite resistance or other disparasite management history should be used to determine if the product is appropriate for the herd, prior to the use of any superpost parameter designation, and excreted irremental Safety; bermectin and exserted irremental residues may adversely effect aquanticate or other disparasite. The not comparament parameter is required in the product is appropriate for the herd, prior to the use of any superpost parameter and excitate some content of the product is appropriate for the herd, prior to the use of any superpost parameter and excitate the development and except the present an account of the starting in the sure of a focal legg count reduction to another development of interactions. The comparament of the starting is a former and the surface of the sample, with the use of a focal legg count reduction to a development of the sample, with the use of a focal legg count reduction to a development of the sample, with the use of a focal legg count reduction to a focal legg count reduct

INFORMATION FOR HORSE OWNERS: Swelling and liching reactions after treatment with MERINETII Givernettin paste) have occurred in harses carrying beary infections of neck recovering the control of the past of mixed links dying in large numbers. Symptomatic treatment may be advisable. Consult your vectorisation should any such executions occur. Healing of summer some involving extensive tissue changes may require other appropriate therapy in conjunction with treatment with IVEXINCTINE. Reinfection, and measures for its prevention, should also be considered. Consulty your vectorisation in the conditioned countly your vectorisation in the conditioned consult practice.





IVERMECTIN ivermectin paste **Product Information** OTC ANIMAL DRUG Item Code (Source) NDC:86010-100 **Product Type**

Pouto	At Ad	ministr	ation.
noute	UI AU	111111361	alivii

ORAL

Active Ingredient/Active Moiety

ı	, ,		
	Ingredient Name	Basis of Strength	Strength
	Ivermectin (UNII: 8883YP2R6D) (IVERMECTIN - UNII:8883YP2R6D)	Ivermectin	18.7 mg in 1 g

_				
Da		24	In.	7
Га	ck	au	ш	и
_	_	_		•

	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	1	NDC:86010-100-01	6.08 g in 1 CARTON		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
ANADA	ANADA200326	12/12/2013		

Labeler - JEFFERS (094385218)

Registrant - Bimeda, Inc. (060492923)

Establishment				
Name	Address	ID/FEI	Business Operations	
Bimeda-MTC Animal Health		256232216	manufacture	

Revised: 4/2022 JEFFERS